

## EXHIBIT A

Evaluation of the Tablet Compression properties of various sources of Dextrose Monohydrate

### TEST #1

Applicants prepared three batches of 1185 mg chewable tablets, where 650 mg of dextrose monohydrate from CEREOSE, C\*PHARMDEX 02011, and LYCADEX® PF (Roquette Pharma) were evaluated. The blend was compressed on a Manesty Betapress using 19/32" extra deep concave punches.

Using **Corn Products Cerelose**, at a compression force of 10.5 KN,

-tablet hardness = 3.2 kp

-friability testing of 5 tablets = **1 broke** at **97** revolutions, and the **4 others passed** **100** revolutions

Using **Roquette Lycadex PF**, at a compression force of 10.5 KN,

-tablet hardness = 2.7 kp

-friability testing of 5 tablets = **all broke** by **79** revolutions

Using **Cerestar CPharm 02010**, at a compression force of 10.5 KN,

-tablet hardness = 1.8 kp

-friability testing of 5 tablets = **all broke** by **36** revolutions

### TEST #2

Applicants prepared three batches of 1187.5 mg chewable tablets, where 650 mg of dextrose monohydrate from CEREOSE, C\*PHARMDEX 02011, and LYCADEX® PF (Roquette Pharma) were evaluated. The blend was compressed on a Manesty Betapress using 19/32" extra deep concave punches.

Using **Corn Products Cerelose Coarse**, at a compression force of 11.5 KN,

-tablet hardness = 3.6 kp

-friability testing of 5 tablets = **none broke** after **50** revolutions

Using **Roquette Lycadex PF**, at a compression force of 12 KN,

-tablet hardness = 1.7 kp

-friability testing of 5 tablets = **5 of 5 broke** after **50** revolutions

Using **Cerestar CPharm 02010**, at a compression force of 12 KN,

-tablet hardness = 2.1 kp

-friability testing of 5 tablets = **4 of 5 broke** after **50** revolutions

## EXHIBIT B

### MANUFACTURER's INFORMATION

#### Corn Products U.S.

**Cerelose® Coarse Grade Dextrose NF** is a dextrose for use as an excipient in pharmaceutical applications and is suitable for direct compression tabletting operations.

#### Roquette Lycadex

##### **LYCADEX® PF**

Nature's sweet medicine

Dextrose or glucose is the physiological sugar used as an active isotonic agent or a carbohydrate energy source in parenteral infusion or injectable therapies. It is also an essential ingredient in the formulation of peritoneal dialysis and haemodialysis solutions.

These mass medication products can be lifesaving and their quality is critical. The dextrose solutions used in these therapies have to be of the very highest quality.

With LYCADEX® PF, Roquette has pioneered the development of this level of quality in a pyrogen-free Dextrose Monohydrate product that has set a standard recognised around the world.

#### Cargill's (Formerly Cerestar) C\*Pharm 02010

<b>Description</b>	C*Pharm 02010 is the pyrogen and endotoxin controlled grade of monohydrated crystalline D-glucose (dextrose) consisting of odorless, multi-granular white crystals.	
<b>Properties</b>	C*Pharm 02010 is readily water soluble with a negative heat of solution. C*Pharm 02010 is characterized by a high nutritive value, excellent digestibility and direct assimilation in the human body.	
<b>Product Data</b>	Moisture	% 8.3
	Specific rotation	+ 52.9
	Solubility in water (25° C)	% d.b 51
	Filterability (35% d.b, 2 bar, 40 C, 0.2μ m)	
	750 ml min	4.5
	1500ml min	9
	Pyrogens (rabbit test)	meets Ph. Eur.III
	Endotoxins (LAL test) EU/g (d.s)	0.6
	Total bacteria mesophiles	CFU/g 1
	Total yeasts	CFU/g 2
	Total moulds	CFU/g 1
<b>Applications</b>	Parenteral nutrition	
	Dialysis and serum applications	